

REMARKS

The final Office Action mailed July 31, 2008, has been received and carefully considered.

Claims 1, 2, 13-15, and 33-51 are pending in the Application and are submitted to be in allowable condition for reasons given in the following.

The rejection of claims 1, 2, 13-15, and 33-51 under 35 U.S.C. §103(a) as unpatentably obvious over *Hu* (CN 1,168,278 A) is respectfully traversed.

1. The Examiner considers that *Hu* discloses all five of Applicants' claimed ingredients in one composition and in similar range amounts for the treatment of specified types of cancers. Applicant respectfully draws the Examiner's attention to a typographical error in the Office Action on page 3, line 1, where "pangolin at 2-6g" should be "pangolin at 2-16g".
2. The Examiner points to Example 6 on page 37 [sic 38] of the translation of *Hu* as containing 150 g. of each of five ingredients so that the ratio of the ingredients is 1:1:1:1:1 which falls within Applicant's claimed range.
3. *Hu* discloses a traditional Chinese medicine comprising six active ingredients in combination: semen momordicae, hydnocarpus seed, pangolin scales, rhubarb, licorice and bamboo shavings. However, Example 6 lists one composition containing five active ingredients, as shown in the following comparative table:

<i>Hu</i> discloses a traditional Chinese medicine comprising six active constituents in combination:	Hu Example 6, page 38 discloses an anti-tumor capsule including five ingredients:	The present Invention claims a traditional Chinese medicine composition having anti-tumor properties, "comprising" (see claims 1 and 2), or "consisting essentially of" (see claims 36 and 37), or "consisting of" (see claims 44 and 45):
5-18 g. of semen momordicae;	150 g. of Mormordica	0.8-1.4 parts by weight of cochinchina momordica seed;
3-18 g. of hydnocarpus seed (also known as "chaulmoogra" and "Gynocardia odorata" as the Examiner comments);	150g. of Gynocardia odorata	1 part by weight of hydnocarpus;
2-6 g. of pangolin scales;	150 g. Pangolin	0.5-1.1 parts by weight of pangolin scales;
5-20 g. of rhubarb;	150g. Rhubarb	0.8-1.3 parts by weight of rhubarb; and
15-25 g. of licorice (also known as "sweet root"); and	150g. of sweet root	1-1.5 parts by weight of licorice root.
bamboo shavings,	None listed.	None.
that have a curative effect on gastric cancer and liver cancer, and the like.		The present invention additionally claims use of the compositions "for treating a patient afflicted with cancer..." (see claims 13-15, 33-35, 38-43, and 46-51).

4. Applicant presents the following comments for clarification.

5. Mistaken disclosure - Applicant and colleges met the inventor of the *Hu* reference, Mr. Hu. Mr. Hu confirmed the following facts. His invention discloses a

Chinese medicine composition comprising six kinds of ingredients. Example 6 of the specification disclosed a composition including only five kinds of ingredients by mistake, i.e., Example 6 inadvertently omitted the bamboo shaving ingredient which is known to reduce the toxicity of other ingredients. This inconsistency between the claims of *Hu* and Example 6 of *Hu* was due to a drafting error which went unnoticed. That is, Mr. Hu's attorney erroneously excluded bamboo shaving from Example 6 while drafting the Hu Patent Application. The erroneous composition of Example 6 is thus inadvertently similar to the composition of the present invention. However, Applicant draws the Examiner's attention to the fact that the effect of Example 6 of *Hu* was not demonstrated by any test reported in the *Hu* disclosure.

6. Non-obvious despite disclosure error - Applicant submits that one of ordinary skill in this art after reading the Hu disclosure as a whole would consider that *Hu* discloses a composition including six ingredients in combination because that is the overall thrust of the text and claims. Applicant therefore submits that, despite the erroneous disclosure of a five-ingredient composition in Example 6 of *Hu*, the present invention would still be non-obvious for the artisan for the reasons discussed in greater detail in the following.

7. Safety regulations - A Chinese medicine composition is expected to be safe for the body of the patient. In fact, according to the rules of the pharmaceuticals management department in virtually every country, a safety test is to be performed before pharmacodynamical and clinical testing. Thus, safety is the primary factor to be considered as one of ordinary skill in this art would know. Applicant submits that from the perspective of an artisan, as well as in accordance with prior Chinese medicine knowledge, all six ingredients in the composition of *Hu* would be necessary because only compositions including all six ingredients were tested and found to be safe by *Hu*.

8. Testing on six-ingredient compositions only - All the test results in *Hu* show the effect of composition comprising six kinds of ingredients. It is clear from *Hu* that there is no test data which relates to the composition of Example 6. It is known that Chinese

medicine belongs to the field of pharmaceutical chemistry which is a scientific subject that depends on experimentation. Whether an invention in the field pharmaceutical chemistry can be carried out and what its effects would be are difficult to predict. Tests need to be conducted and results confirmed by repeated testing. Thus, Applicant submits that an artisan with knowledge of *Hu* as a whole would be inclined to view Example 6 as suspect, i.e., the artisan would get a feeling that an error in disclosure had occurred so that the artisan would not expect that the composition of Example 6 would have a result in accordance with test results reported for the six-ingredient compositions disclosed and claimed everywhere else.

9. Toxic ingredients raise safety issues if toxicity-reducing ingredient eliminated – Semen momordicae is known to have the serious side effects of causing heartbeat-quickening, breath-shortening and blood-pressure-falling. Hydnocarpus seed can cause stimulation such as pain, anaemia, hematuria, swirling and insomnia. Thus, an artisan would know that a composition including two such known toxic ingredients can enormously increase the toxicity of the composition even though an anti-cancer was obtained. The artisan would additionally know that if the toxicity of a composition is not well controlled, it cannot be applied clinically. According to prior Chinese medicine practice, bamboo shaving can reduce the toxicity of the above two ingredients. Thus, Applicant submits that an artisan would be aware of these points and would question elimination of bamboo shavings in Example 6, particularly when reading the *Hu* disclosure as a whole. Moreover, without testing, the artisan would not be able to predict whether the bamboo shavings ingredient can be removed safely or not.

10. Curative effect reduction possible - Furthermore, some soluble compounds contained in bamboo shavings can go through the periosteum, the meanings, and the tumor envelope. As is additionally known, constituents of bamboo shavings can assist pangolin scales to reach the whole of the body. Thus, the artisan would be aware that the removal of the sixth ingredient, bamboo shavings, as erroneously shown in Example 6 of *Hu*, might reduce the curative effect of the composition. Applicant

therefore submits that the artisan would not be able to infer from Example 6 of *Hu* that a composition containing five ingredients, but no bamboo shavings, would have a curative effect in accordance with that of a composition containing six ingredients. Applicant additionally submits that the artisan would be inclined to think that Example 6 was a comparative example providing results that were not only not included in *Hu*'s claims but also not reported in *Hu*'s reporting of test results.

11. Clinical tests require a large investment - As mentioned above, the effect of a composition in pharmaceutical chemistry needs to be demonstrated by test results. Pharmacodynamical and clinical test are not simple tests. Rather such testing requires huge financial, material and human resources, and testing generally takes a long time. Also, because the content of each ingredient in a composition has a relationship to that of the other ingredients, a huge number of formulations need to be tested. Thus, it is an arduous task to optimize a Chinese medicine composition. Applicant therefore submits that, under circumstances as here where an artisan would doubt whether a five-ingredient composition according to Example 6 of *Hu* would be safe and/or effective, there would be less motivation for the artisan to spend huge financial, material and human resources to research this point. Additionally, even if an artisan would seek a better composition based on the disclosure of Example 6 of *Hu*, such an effort would require creative work, not just simple testing.

12. Composition ratios compared - The following table presents Applicant's normalization of the amounts of ingredients of *Hu* and the present invention for the Examiner's convenience. The content ranges of *Hu* is much wider than that of the present invention; that is, the content ranges of *Hu* overlap those of Applicant's composition. Applicant therefore submits that, if an artisan would seek a better composition based on the disclosure of Example 6 of *Hu*, such an effort would require creative work, not just simple testing.

	Hydno- carpus seed	semen momor- dicae	pangolin scales	rhubarb	licorice	bamboo shaving
CN1168278A	3-18g	5-18g	2-16g	5-20g	15-25g	5-20g
Recipe Max:	3g	18g	16g	20g	25g	
Ratio Max:	1	6	5.3	6.67	8.33	
Recipe Min:	18	5	2	5	10	
Ratio Min:	1	0.28	0.11	0.28	0.56	
Range:	1	0.28-6	0.11-5.3	0.28-6.67	0.56-8.33	
This invention	1	0.8-1.4	0.5-1.1	0.8-1.3	1-1.5	
Ratio calculated	1.5	2.5	1	2.5	7.5	
by the Examiner	1	1.67	0.67	1.67	5	

13. In summary - Since the five-ingredient composition of Example 6 of *Hu* erroneously left out the intended sixth ingredient, bamboo shavings, and since an artisan would view Example 6 of *Hu* as questionable in terms of safety, effectiveness, and worthy of the investment to test, Applicant submits that the disclosure of *Hu* may not be fairly said to render obvious the present invention according to claims 1, 2, 13-15, and 33-51 so that no *prima facie* case of obviousness is submitted to exist and this remaining ground of rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants submit that claims 1, 2, 13-15, and 33-51, and the Application are in condition for allowance. Reconsideration and passage of this case to issue are therefore requested.


Should the Examiner consider that a conference would help to expedite the prosecution of this Application, the Examiner is invited to contact the undersigned to arrange for such an interview.

No fee is believed due. If any fee is deemed due, the Commissioner is hereby authorized to charge the same to our Deposit Account No, 18-0002 and is requested to advise us accordingly.

Respectfully submitted,

October 29, 2008

Date



Steven M. Rabin (Reg. No. 29,102)

Rabin and Berdo PC

CUSTOMER NO. 23995

1101 - 14th Street, N.W., Suite 500

Washington, D.C. 20005

Tel.: (202) 371-8976

Fax: (202) 408-0924

SMR/AJW:ac